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PHILIPS

Philips Medical Systems

K 000819

510(K) Summary

In accordance with the requirements of the Safe Medical Device Act, Philips Medical Systems North America Company herewith submits a 510(K) summary of safety and effectiveness for the following device.

SUBMITTER NAME / ADDRESS: Philips Medical Systems North America Company
710 Bridgeport Avenue
Shelton, CT 06484-0917

CONTACT PERSON / TEL NO: Frank Gianelli
Tel No: (203) 926-7729

DATE SUMMARY PREPARED: March 9, 2000

ESTABLISHMENT NO.: 1217116

TRADE/PROPRIETARY NAME: **CT Secura MV**

COMMON/USUAL NAME: CT X-ray System

CLASSIFICATION NAME: Computed Tomography X-ray System
(Class II; Tier 2; 90JAK, 21 CFR 892.1750)

PREDICATE DEVICE(S): CT Secura

DEVICE DESCRIPTION:

The **CT Secura MV** is a whole body scanner based on optical slipring technology. With the **CT Secura MV**, Philips introduces a new product to its CT Vision product family. The **CT Secura MV** is based on and includes the same technological features of existing CT Vision computed tomography systems; i.e. Philips CT Secura and Philips CT Aura. The one difference is that the **CT Secura MV** uses a solid state multi-detector array (Philips marketing name: MultiView or MV) for multislice scanning. The MultiView multi-detector array enables the simultaneous data acquisition of two or more slices in a single rotation. The result is the acquisition of complete volumes of data in half or less time than with the standard single array version. MultiView will also be an option for Philips Medical Systems' CT scanners.

The **CT Secura MV** is comprised of two main parts:

- The operators console (back-end part) to enable scanning and advanced image processing. It is comprised of a data acquisition part and a post-processing part with separate monitors and keyboards for each part.
- The gantry and patient table (front-end part). The gantry and table movements are controlled via the control panels on either side of the gantry. Patient positioning laser lights are mounted both externally on the gantry as an aid to patient positioning and at the scan plane.

Other then the multi-detector array, all scanning facilities and features of the **CT Secura MV** are the same as with predicate device CT Secura. The **CT Secura MV** can interface with selected PACS and RIS systems by using standard technology with UNIX based software and standard interfaces such as TCP/IP and DICOM 3. The **CT Secura MV** can be integrated with the Philips Inturis™ information management products. The **CT Secura MV** can allow for the remote accessing of CT images via NetView. NetView allows authorized users to access images and reports via standard internet web browsers for non-diagnostic viewing on a PC or other computer.

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INTENDED USE:

The **CT Secura MV** is a whole body Computed Tomography (CT) system which is a diagnostic X-ray system intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission of data from the same axial plane taken at different angles. It includes signal analysis and display equipment, patient and equipment supports, component parts and accessories which are used in combination with signal and image processing software to facilitate the relative localization of anatomy with gray-scale representation of density relative to water utilizing Houndsfield indices with or without contrast mediums. It is used for the display, storage and analysis of digital diagnostic CT images. The **CT Secura MV** is intended for use by a physician in the diagnosis and planning phases of patient conditions and treatment.

SUBSTANTIAL EQUIVALENCE INFORMATION:

The **CT Secura MV** is considered a modification of, and substantially equivalent to Philips Medical Systems' CT Secura. Predicate device, CT Secura was originally cleared under the name Tomoscan AV-NT (ref: K991278) for which the name was later changed to CT Secura (via 10/13/1999 addendum letter to FDA for K991278). Other comparable and substantially equivalent devices are GE Medical Systems' Lightspeed QXi CT Scanner System (ref: K980176) and Toshiba Medical Systems' Multislice Upgrade kit for the Aquilion CT Scanner System (Aquilion/Multi) (ref: K990134).

TECHNOLOGICAL CHARACTERISTICS:

The **CT Secura MV** is a whole body x-ray computed tomography scanner that has the same technological characteristics as predicate device, CT Secura. The only difference is **CT Secura MV** uses a solid state multi-array detector (MultiView) for multislice scanning. MultiView will also be an option for Philips Medical Systems' CT scanners.

The **CT Secura MV** is also similar in technological characteristics to predicate devices, GE Medical Systems' Lightspeed QXi CT Scanner System and Toshiba Medical Systems' Multislice Upgrade kit for the Aquilion CT Scanner System (Aquilion/Multi).

SAFETY INFORMATION:

The **CT Secura MV** introduces no new safety issues to the CT Vision family of CT systems other then those already known with these systems. These devices must comply with the appropriate sections of the Radiation Control for Health and Safety Act. The Philips CT Secura MV and its labeling complies with the applicable requirements of the Federal X-ray Performance standards 21 CFR 1020.30, 1020.33. A Product Report according to 21 CFR 1002.10 will be submitted to FDA prior to the first delivery of the CT Secura MV. The CT Secura MV also complies with the international standard IEC-60601-1, national safety standard UL-2601-1 and the ACR/NEMA DICOM Version 3 digital imaging communication standard. The results of a hazard analysis, combined with the appropriate preventive measures taken indicate that the device is of minor level of concern as per the May 29, 1998 issue of "The Guidance for the Content of Premarket Submission for Software Contained in Medical Devices".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2000

Frank Gianelli
Senior Regulatory Affairs Specialist
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Re: K000819
Philips CT Secura MV
Dated: March 9, 2000
Received: March 13, 2000
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Gianelli:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K000819

Device Name : Philips CT SECURA MV

Indications For Use :

The CT SECURA MV is a whole body Computed Tomography (CT) system which is a diagnostic X-ray system intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission of data from the same axial plane taken at different angles. It includes signal analysis and display equipment, patient and equipment supports, component parts and accessories which are used in combination with signal and image processing software to facilitate the relative localization of anatomy with gray-scale representation of density relative to water utilizing Houndsfield indices with or without contrast mediums. It is used for the display, storage and analysis of digital diagnostic CT images. The CT SECURA MV is intended for use by a physician in the diagnosis and planning phases of patient conditions and treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000819